510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Submitter's Name: Crosstrees Medical, Inc.

Address: 4735 Walnut Street, Suite E
Boulder, CO 80301
Telephone: 720-880-5811
Fax: 303-484-6099

Contact Person: Robert Scribner
Telephone: 720-880-5811

DEC 0 6 2013

Date Prepared: November 1, 2013

Name of Device and Name/Address of Sponsor
Crosstrees® PVA Pod Device

Common Name
Bone Cement Delivery Device

Classification Name
888.3027 – Cement, Bone, Vertebroplasty
888.1100 - Arthroscope

Predicate Devices
Crosstrees® PVA Pod Device (K130089)

Intended Use
The Crosstrees® Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.

Device Description
The Crosstrees® PVA Pod device is designed to deliver bone cement to the fractured vertebral body in a controlled manner without the need for an additional permanent implant other than the bone cement. The device consists of a shaft assembly for delivery of PMMA cement to a fabric barrier. Following cement delivery, the fabric barrier is opened and withdrawn from the vertebral body. The Crosstrees® PVA Pod device is made from a variety of materials commonly used in orthopedic and radiological procedures including stainless steel and polymers. The device is available in either a 2.0 mL or 3.0 mL fill capacity. The device is provided with a number of class I tools that are used for surgical access and delivery of the Pod to the surgical site, as well as preparation and delivery of bone cement.

Substantial Equivalence

The Crosstrees® PVA Pod has the same intended use, indications for use, and principles of operation, as well as very similar technological characteristics as its predicate device. The minor technological differences between the Crosstrees® PVA Pod and its predicate device, change in the pod fabric dimensional specification, and the removal of a yarn texturing process, raise no new issues of safety or effectiveness questions. Risk assessment of the modification and design verification testing, performed to support design control activities, demonstrates that the Crosstrees® PVA Pod performs as intended and is as safe and effective as the previously cleared device. Thus, the Crosstrees® PVA Pod is substantially equivalent.

Device	**Crosstrees® PVA Pod**	**Predicate Crosstrees® PVA Pod (K130089)**
Intended Use	The Crosstrees® Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.	The Crosstrees® Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.
Materials	Woven Polymer, Stainless Steel, UV Curable Adhesives, Thermoplastic Injection Molded Handles/Hubs	Woven Polymer, Stainless Steel, UV Curable Adhesives, Thermoplastic Injection Molded Handles/Hubs
Major Components	Expandable Member, Delivery Shaft	Expandable Member, Delivery Shaft
Expandable Member Material	Woven Polymer Fabric Pod (Polyester)	Woven Polymer Fabric Pod (Polyester)
Expandable Member Length	20mm	15, 20mm
Expandable Member Max Volume	2 mL	2 mL, 3mL
Expandable Member Shape	Cylindrical/Elliptical	Cylindrical/Elliptical
How Supplied	Sterile Single Use (ANSI/AAMI/ISO 11137:2006 Gamma Irradiation)	Sterile Single Use (ANSI/AAMI/ISO 11137:2006 Gamma Irradiation)

Performance Data

The Crosstrees® PVA Pod has the same sterilization process, same packaging, and is comprised of the same materials of construction as the predicate device. Device modifications have been assessed through Crosstrees design control process and the data generated demonstrates that the Crosstrees® PVA Pod device meets all performance characteristics and design specifications, thus supporting substantial equivalence to the predicate device. In all instances, the Crosstrees® PVA Pod device functioned as intended.

Conclusion

The Crosstrees® PVA Pod has the same intended use, indications for use, and principles of operation, as well as very similar technological characteristics as its predicate device. Testing conducted to support design control activities confirms that the product performs as intended. Therefore, the Crosstrees® PVA Pod is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Crosstrees Medical, Incorporated
% Ms. Janice Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K133372
Trade/Device Name: Crosstrees® PVA Pod Device
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: November 12, 2013
Received: November 12, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133372

Device Name: Crosstrees® PVA Pod Device

Indications for Use:

The Crosstrees® Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133372